FORM PTO 1390
(REV 11-98) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: GAMBRO-250

U.S. APPLICATION NO. (If known, see 37 CFR 1 5): 09/786930

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATES	PRIORITY DATE CLAIMED
PCT/ SE99/01541	6 September 1999	10 September 1998

TITLE OF INVENTION: APPARATUS FOR MONITORING A FLUID CONDUIT

APPLICANT(S) FOR DO/EO/US: Olof EKDAHL, et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U S.C 371
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U S C. 371
3. [X] This is an express request to promptly begin national examination procedures (35 U S C. 371 (f)).
4. [X] The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. [X] A copy of the International Application as filed (35 U S C. 371 (c)(2))
   - a [ ] is attached hereto (required only if not transmitted by the International Bureau).
   - b [X] has been communicated by the International Bureau
   - c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] An English language translation of the International Application as filed (35 U.S C 371 (c)(2))
7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S C. 371 (c)(3))
   - a. [ ] are attached hereto (required only if not communicated by the International Bureau).
   - b [ ] have been communicated by the International Bureau.
   - c [ ] have not been made; however, the time limit for making such amendments has NOT expired
   - d. [X] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C 371 (c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). (Unexecuted)
10. [ ] An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U S.C. 371 (c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. [X] An Information Disclosure Statement under 37 CFR 1 97 and 1 98 w/PTO-1449, 6 references
12. [ ] An assignment document for recording A separate cover sheet in compliance with 37 CFR 3 28 & 3.31 is included.
13. [X] A FIRST preliminary amendment
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [X] A substitute specification.
15. [ ] A change of power of attorney and/or address letter
16. [X] Other items or information:

-Substitute Abstract
-Marked-up Specification
-Copy of International Application as published
-Copy of International Preliminary Examination Report
-Copy of International Search Report
-Four (4) Sheets Formal Drawings

EXPRESS MAIL LABEL NO. EL646757875 US
DATE: March 12, 2001

U.S. APPLICATION NO. (if known, see 37 CFR 1 5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
09/786930	PCT/ SE99/01541	GAMBRO-250

17 [X] The following fees are submitted:

CALCULATIONS PTO USE ONLY

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) – (5)):

[X]	Neither international preliminary examination fee (37 CFR 1 482) nor international search fee (37 CFR 1 445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO . .	$1,000.00
[ ]	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	$860 00
[ ]	International preliminary examination fee (37 CFR 1 482) not paid to USPTO but international search fee (37 CFR 1 445(a)(2)) paid to USPTO . .	$710 00
[ ]	International preliminary examination fee paid to USPTO (37 CFR 1 482) but all claims did not satisfy provisions of PCT Article 33(1)-(4)	$690 00
[ ]	International preliminary examination fee paid to USPTO (37 CFR 1 482) and all claims satisfied provisions of PCT Article 33(1)-(4)	$100 00

ENTER APPROPRIATE BASIC FEE AMOUNT =				1,000.00	
Surcharge of $130.00 for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).					
CLAIMS	**NUMBER FILED**	**NUMBER EXTRA**	**RATE**		
Total claims	*18 - 20 =		x $18.00		
Independent claims	2 - 3 =		x $80.00		
MULTIPLE DEPENDENT CLAIM(s) (if applicable)			+ $270.00		
TOTAL OF ABOVE CALCULATIONS =				1,000.00	
[ ] Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½.					
SUBTOTAL =				1,000.00	
Processing fee of $130.00 for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +					
TOTAL NATIONAL FEE =				1,000.00	
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). Assignment must be accompanied by appropriate cover sheet (37 CFR 3.28, 3.31) + ($40.00 per property)					
TOTAL FEES ENCLOSED =				1,000.00	

* As In Preliminary Amendment

Amount to be: Refunded

Charged

a. [ ] A check in the amount of _____ to cover the above fees is enclosed.

b [X] Please charge my Deposit Account No. 12-1095 in the amount of $ 1,000.00 to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to my Deposit Account No. 12-1095 . A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Lerner, David, Littenberg, Krumholz & Mentlik, LLP
600 South Avenue West
Westfield, NJ 07090
Telephone 908 654-5000
Facsimile 908 654-7866

Signature

ARNOLD H. KRUMHOLZ
Name

25,428
Registration Number

PATENT
GAMBRO 3.3-250

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of EKDAHL *et al.*	:	
	:	Group Art Unit:
International Application No. PCT/SE99/01541	:	Examiner:
International Filing Date: 6 September 1999	:	Date: March 12, 2001
For: APPARATUS FOR MONITORING A FLUID CONDUIT	:	

Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Preliminary to initiation of the prosecution of the above-identified pending U.S. patent application, the following amendments and remarks are respectfully submitted.

IN THE ABSTRACT

Please delete the Abstract as filed and substitute therefor the attached revised Abstract.

IN THE SPECIFICATION

Please amend the Specification in accordance with the attached revised Specification.

IN THE CLAIMS

Please cancel claims 1-13 and add new claims 14-31.

14. (NEW) Apparatus for determining the presence of a fluid conduit at a predetermined location and at least one characteristic of the contents of said fluid conduit, said apparatus comprising a light source for generating radiated light in a direction towards said predetermined location, whereby when said fluid conduit is present at said predetermined location said radiated light passes in a direction through said fluid conduit, a first optical sensor for detecting said radiated light passing

through said fluid conduit, and a second optical sensor for detecting said radiated light which is reflected by said fluid conduit.

15. (NEW) The apparatus of claim 14 in combination with a control device.

16. (NEW) The apparatus of claim 15 wherein said control device comprises a device for the extracorporeal treatment of blood.

17. (NEW) The apparatus of claim 14 wherein said second optical sensor is integrally formed with said light source.

18. (NEW) The apparatus of claim 14 including a housing, and wherein said light source, said first optical sensor and said second optical sensor are disposed in said housing.

19. (NEW) The apparatus of claim 18 in combination with a control device.

20. (NEW) The apparatus of claim 19 wherein said housing constitutes a portion of said control device.

21. (NEW) The apparatus of claim 14 including a first waveguide for transmitting said radiated light from said light source to said predetermined location and for transmitting said radiated light reflected by said conduit to said second optical sensor, and a second waveguide for transmitting said radiated light which passes through said fluid conduit to said first optical sensor.

22. (NEW) The apparatus of claim 21 in combination with a control device.

23. (NEW) The apparatus of claim 22 including a housing, and wherein said light source, said first optical sensor, and said second optical sensor are disposed in said housing, and including a fluid conduit holder for holding said fluid conduit at said predetermined location, said fluid conduit holder disposed on said housing, said first and second waveguides being integrated with said fluid conduit holder.

24. (NEW) The apparatus of claim 22 wherein said first waveguide is disposed at a location adjacent to said fluid conduit whereby an air gap is created therebetween.

25. (NEW) The apparatus of claim 14 wherein said light source generates said radiated light having a predetermined wavelength and a predetermined modulation.

26. (NEW) The apparatus of claim 25 wherein said predetermined wavelength comprises a wavelength in the range of infrared radiation, and wherein said predetermined modulation comprising a substantially square pulse sequence.

27. (NEW) The apparatus of claim 15 wherein said control device includes a control unit, and wherein said first and second optical sensors are electrically connected to said control unit, said first optical sensor providing a first signal and said second optical sensor providing a second signal.

28. (NEW) The apparatus of claim 27 wherein said control device includes comparing means for comparing said first and second signals with predetermined signal values, whereby when said first signal is at a predetermined high level and said second signal is at a predetermined low level, said comparing means determines that said fluid conduit is not present at said predetermined location, when said first signal is at a predetermined medium level and said second signal is at a predetermined high level, said comparing means determines that said fluid conduit is present at said predetermined location and said fluid is not present in said fluid conduit, when said first signal is at a predetermined high level and said second signal is at a predetermined high level, said comparing means determines that said fluid conduit is present at said predetermined location and said fluid comprises a transparent fluid, when said first signal is at a predetermined low level and said second signal is at a predetermined high level, said comparing means determines that said fluid conduit is present at said predetermined location and said fluid comprises an opaque fluid, when said first signal is at a predetermined low level and pulses at a predetermined high level, and said second signal is at a predetermined high

level, said comparing means determines that said fluid conduit is present at said predetermined location and said fluid comprises an opaque fluid containing air bubbles, and when said first signal is at a predetermined low or medium level and said second signal is at a predetermined low level, said comparing means determines that an error condition exists.

29. (NEW) The apparatus of claim 15 wherein said control device comprises a dialysis monitor.

30. (NEW) A method for determining the presence of a fluid conduit at a predetermined location and at least one characteristic of said contents of said fluid conduit, said method comprising directing radiated light towards said predetermined location whereby when said fluid conduit is present at said predetermined location said radiated light passes in a direction through said conduit, detecting a first portion of said radiated light passing through said fluid conduit and detecting a second portion of said radiated light which is reflected by said fluid conduit.

31. (NEW) The method of claim 30 including comparing said first and second portions of said radiated light with predetermined values therefor whereby when said first portion of said radiated light is at a predetermined high level and said second portion of said radiated light is at a predetermined low level, determining that said fluid conduit is not present at said predetermined location, when said first portion of said radiated light is at a predetermined medium level and said second portion of said radiated light is at a predetermined high level, determining that said fluid conduit is present at said predetermined location and said fluid is not present in said fluid conduit, when said first portion of said radiated light is at a predetermined high level and said second portion of said radiated light is at a predetermined high level, determining that said fluid conduit is present at said predetermined location and said fluid comprises a transparent fluid, when said first portion of said radiated light is at a predetermined low level and said second portion of said radiated light is at a predetermined high

level, determining that said fluid conduit is present at said predetermined location and said fluid comprises an opaque fluid, when said first portion of said radiated light is at a predetermined low level and pulses at a predetermined high level, and said second portion of said radiated light is at a predetermined high level, determining that said fluid conduit is present at said predetermined location and said fluid comprises an opaque fluid including air bubbles, and when said first portion of said radiated light is at a predetermined low or medium level and said second portion of said radiated light is at a predetermined low level, determining that an error condition exists.

REMARKS

The above-noted cancellation of claims 1-13, and addition of new claims 14-31, as well as the submission of a new Abstract and revisions to the Specification, are respectfully submitted prior to initiation of the prosecution of this application in the U.S. Patent and Trademark Office.

The above-noted new claims are respectfully submitted in order to more clearly and appropriately claim the subject matter which applicant considers to constitute his inventive contribution. No new matter is included in these amendments. In addition, the revisions to the Abstract and Specification are submitted in order to clarify and correct the Abstract and Specification and to conform them to all of the requirements of U.S. practice. No new matter is included in these amendments.

In view of the above, it is respectfully requested that these amendments now be entered, and that prosecution on the merits of this application now be initiated. If, however, for any reason the Examiner does not believe such action can be taken, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any objections which he may have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge applicant's Deposit Account No. 12-1095 therefor.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP

ARNOLD H. KRUMHOLZ
Reg. No. 25,428

600 South Avenue West
Westfield, NJ 07090-1497
Telephone: (908) 654-5000
Facsimile: (908) 654-7866

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APPARATUS FOR MONITORING A FLUID CONDUIT

The present invention concerns an apparatus for detecting the presence of a fluid conduit and at least one characteristic of the content of the fluid conduit, the apparatus being disposed on a control device, for example, for the extracorporeal treatment of blood, with a light source, the radiation of which is directed towards the conduit and through the same, and with an optical sensor for the radiation emitted by the light source that detects the radiation directed through the fluid conduit.

The apparatus according to the invention is intended for use with control devices for dialysis, which are also termed monitors. In this case, the fluid conduit may be filled with blood, a rinsing liquid or air.

TECHNICAL BACKGROUND

A series of apparatus are known for monitoring a fluid conduit or tube that is connected to a dialysis monitor. For example, air detectors are known which check the blood in the fluid conduit that is passed back to the patient for air or air bubbles. Furthermore, blood detectors are known that check the dialysate liquid passed back by the dialyser for blood, and thus are able to determine the presence of a leak in the dialyser membrane. As soon as these detectors determine air or

membrane. As soon as these detectors determine air or blood in the fluid passed through the conduit, a control unit of the monitor connected with the detectors sets off an alarm to prevent an endangerment of the patient. Moreover, an alarm is set off when a fluid conduit is absent, provided that these detectors are designed to monitor the fluid conduit also.

Normally, the known apparatus includes a photoelectric section that is arranged such that it passes through the essentially transparent fluid conduit. For example, an apparatus is known from DE 37 68 033 in which the infrared light from a source is transmitted using a waveguide to a tube or to a recess in a tube support that is intended to hold the tube. The light is transmitted through a second light section from the recess to a receiver. Depending on whether a tube is mounted or not, and whether it contains essentially transparent rinsing liquid or blood, a varying amount of light reaches the receiver. This sends a signal to an evaluating device or control unit, the signal that is dependent on the amount of received light thereby providing information about the condition of the tube or the contents of the tube. When no tube is present, the light reaches the receiver unfiltered or unattenuated, the receiver then sends a high signal to the evaluating device. If a tube is mounted and filled with air or colourless fluid, for example rinsing fluid, the light reaches the receiver slightly filtered or attenuated, the latter then delivers a medium signal to the evaluating device. If the tube is filled with blood the light will be essentially

completely attenuated and at most a small amount of light will reach the receiver, which then supplies the evaluating device with a low level signal.

However, a disadvantage of this is that with certain tubes, as a result of their shape and composition, a lens effect can arise that distorts the results. In the worst case, this can lead to the same amount of light being transmitted to the receiver when a mounted tube is filled with colourless fluid as when a tube is not mounted. In both cases the receiver generates an identical signal, so that no differentiation is possible between the two states.

An apparatus is known from EP 0 467 805 in which the light source and receiver are each arranged to protrude such that they deform the tube. In this way the astigmatic focusing, the so-called lens effect, which otherwise results from the cylindrical geometry and focuses the light beam onto the receiver, is obviated. However, with this known apparatus only the nature of the fluid present in the tube is determined with the photoelectric section, while the presence of the tube is determined using an electromechanical sensor. As a result of this supplementary electromechanical sensor, the known apparatus is complicated and therefore costly, and at the same time it is unreliable due to the additional possibility of error.

Another apparatus is known from US 5 644 402 which detects both the presence of a tube and also the

characteristics of the fluid transported in the tube with a photoelectric section. To this end, the light source, the receiver and a number of deflectors are disposed in a complicated geometrical arrangement such that, depending on whether the tube is present, and on its content and the resulting differing refraction, the light beam either does not reach the receiver at all, or is once or twice diffracted. It is indeed possible to determine with a photoelectric section whether a tube is present and what characteristics the content has, and it is also possible to achieve greater sensitivity as a result of the partially longer light path. However on the whole, this apparatus is very complex and therefore expensive. In addition, it is highly subject to failure and must be precisely adjusted to the tube in question in order to be able to provide accurate information.

In view of this background it is therefore an object of the present invention to provide an apparatus of the type described in the introduction with which a reliable investigation of the presence of a fluid conduit and also at least one characteristic of the content of the fluid conduit is possible with little expense, to improve the safety of the patient.

DISCLOSURE OF THE INVENTION

This object is achieved with an apparatus of the type mentioned in the introduction that comprises a second optical sensor which detects the radiation reflected from the fluid conduit.

In this way a simply constructed apparatus is provided with which inter alia the presence of a fluid conduit or tube can be reliably ascertained. If a fluid conduit is present, the light beam directed towards the fluid conduit by the light source will be partially reflected, this reflection being detected by the second optical sensor. The latter then generates a signal at a high level that is transmitted to a control unit, for example of a monitor, where it is processed. If no fluid conduit is present then no light can be reflected from the fluid conduit onto the second optical sensor, so that this will generate no signal, or only a signal of low level, and transmit this to the control unit. In this manner, the presence of a fluid conduit can be reliably determined solely by means of the signal from the second optical sensor.

The unreflected light beam, or the unreflected portion of the light beam, is detected by the first optical sensor, which generates a signal dependent on the intensity of the received light radiation and passes this on to the control unit. If no fluid conduit is present, the entire light radiation reaches the first optical sensor unreflected and unfiltered or unattenuated and not weakened, the latter then generates a signal at a high level, and sends this to the control unit. A high-level signal can likewise be generated when a fluid conduit is mounted and contains a transparent liquid, as was described in detail above with reference to the lens effect. However, since a second signal is available from

the fluid conduit, this signal allows the described condition of fluid conduit with transparent fluid to be assigned without ambiguity. The previously existing difficulties in distinguishing these two conditions are thus easily and reliably overcome.

The other characteristics of the fluid conducted through the fluid conduit may also be determined in a simple manner. If the fluid conduit is present and filled only with air, the light beam will be somewhat attenuated, so that a reduced portion will be detected by the first optical sensor. This then generates a signal of medium level, and passes this on to the control unit. If a fluid conduit is present and filled with blood, the light radiation will be essentially completely filtered, and at the most, only a small part of the light radiation will arrive at the first optical sensor. This then generates a low-level signal and sends this to the control unit.

Finally, the presence of air bubbles in a fluid conduit filled with blood can also be easily ascertained. In contrast to the surrounding blood, air bubbles essentially do not attenuate the light beam, so that a substantially unfiltered light beam will pass through the blood containing air bubbles and arrive at the first optical sensor. Thus, when blood containing air bubbles flows past and momentarily allows the light beam to arrive at the first optical sensor substantially unfiltered, the latter generates a short, high-level impulse-like signal, which is superimposed on the low-level signal indicating blood. The presence of air

level signal indicating blood. The presence of air bubbles in the blood can thus be determined simply from the signal shaped from the first optical sensor: a low-level base signal on which are superimposed high-level impulses. In this way a simple measurement of air bubbles is enabled, independently of the type of tube and its position, simply by detecting peaks or impulses on the existing base signal.

Error conditions may also be determined with the apparatus according to the invention, e.g. the presence of an incorrect fluid conduit, or that the light of the light source is too weak, or the light source or the first and/or second sensor is/are faulty. In such cases the first sensor generates a signal of low or medium level and the second sensor generates a signal of low level.

Accordingly, with the apparatus according to the invention the presence of a fluid conduit, at least one characteristic of the content of the fluid conduit and error conditions can be determined easily and reliably as is summarised in the following table.

Table

	Signal from the first sensor	Signal from the second sensor
No fluid conduit	high level	low level
Fluid conduit present, but empty	medium level	high level
Fluid conduit present, filled with transparent fluid	high level	high level
Fluid conduit present, filled with blood	low level	high level
Fluid conduit present, filled with blood, air bubbles	low level with high-level impulses	high level
Error conditions	low or medium level	low level

Error conditions could, for example, be: light source too weak, first and/or second sensor faulty, incorrect fluid conduit.

It should be noted at this instance that when using sensors that, for example give a low-level signal with a strong received light beam and a high level signal with a weak received light beam, the above table is correspondingly reversed. Such an arrangement of the apparatus operating in a kinematically reversed manner is likewise incorporated herein.

The apparatus according to the invention can be further simplified when, in accordance with a preferred embodiment of the invention, the second optical sensor is combined with the light source and, for example, is formed integrally with the light source. The use of such a reflection sensor reduces the number of individual components required for the apparatus, whereby the complexity of the apparatus, and consequently the risk of failure, is further reduced.

It should be noted at this point that this is only a preferred embodiment, and the second optical sensor may be arranged as desired independently of the light source, provided that it captures the light reflected from the fluid conduit. Any desired sensor can be used as an optical sensor, for example, phototransistors, photodiodes or photoresistors.

According to a further preferred embodiment, at least the sensitive electrical and electronic components of the apparatus are integrated in the monitor housing, so that these are protected from external influences, and safety is increased. External influences may, for example, be

moisture, water and glucose or coffee, as well as electromagnetic radiation. Coffee out of a cup that has been placed on the monitor and is knocked over could, for example, run down the monitor and the apparatus, or glucose could accidentally drop on the monitor or be squirted against the apparatus when being administered to a dialysis patient. Electromagnetic radiation can cause the disruption of the signal transmission from the sensors to the monitor device.

In order to ensure the safe transmission of radiation transmitted from the light source towards the fluid conduit, and a safe further transmission towards the first optical sensor, it is advantageous to provide, in accordance with another embodiment, a first waveguide that guides the light or the radiation from the light source to the fluid conduit and the reflected light from the fluid conduit to the second sensor, and a second waveguide that guides light directed towards the fluid conduit to the first optical sensor after it has passed through the fluid conduit. In this way, a defined light path is created that ensures the safe operation of the apparatus irrespective of random external influences.

The waveguides may be made of any desired light-conducting material, such as quartz glass, and may also be formed freely with respect to diameter. However, it is advantageous to form the diameter such that it is smaller than the diameter of the fluid conduit to be detected. This brings the advantage that all the emitted light is utilised for detecting the fluid conduit or its content,

and consequently a higher precision and efficiency is achieved.

However, in place of using waveguides, it is also possible to create a defined light path using mirrors, for example as is disclosed in DE 37 68 033.

According to an alternative embodiment, the first and second waveguides are integrated in a conduit holder or tube holder that is arranged on the monitor housing. By means of this a defined relative association between the fluid conduit and sensors is enabled which further improves the precision and reliability of the measurement.

In this arrangement, the waveguide guiding the light from the light source to the fluid conduit can also be arranged such that it touches the fluid conduit. However, it can also be arranged such that an air gap is present between the end of the waveguide and the fluid conduit. This is necessary in particular when the refractive indexes of the adjacently arranged materials are so similar that no, or only insufficient, reflection is obtained. By providing an air gap, a sufficient difference between the refractive indexes of the adjacently disposed materials, and hence a sufficient reflection of the light beam at the mounted fluid conduit, is obtained.

The light emitted from the light source can be unmodulated light of any desired wavelength. However, it

is advantageous when the emitted light is modulated to allow the reliable detection of light transmitted by the light source and reflected from, or transmitted through, the fluid conduit, irrespective of the surrounding light. For example, light with a wavelength of between 880 and 890 nm and a modulation frequency of 10 kHz may be used. The isolation from surrounding light can be implemented simply by filtering the modulation out of the signal at the detector.

Preferably light in the infrared region is transmitted and modulated, for example, with a square wave pulse sequence, since components for this are known and the work and cost involved in the apparatus will be reduced.

It should also be noted at this stage that when utilising waveguides of glass material, light with a wavelength below 350 nm should not be used, as such short wavelengths are absorbed by glass.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in more detail by means of the preferred embodiments with reference to the accompanying drawings. In these:

Fig. 1 schematically shows parts of a dialysis monitor with an apparatus according to the invention arranged therein;

Fig. 2 shows a schematic view of a preferred embodiment;

Fig. 3 shows a detail with a schematic view of the light radiation in the apparatus according to Fig. 2;

Fig. 4 shows a detail with a schematic view of the light radiation according to a further preferred embodiment; and

Fig. 5 shows a schematic view of the signal processing in the control unit.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the interests of improved clarity only some parts of a dialysis monitor, in which the apparatus according to the invention is utilised, are depicted schematically in Fig. 1.

Blood from a patient is sent to a dialyser 1 through an extracorporeal blood circuit via an arterial tube 3, the blood being moved to the dialyser 1 in the tube 3 by means of a blood pump 7. The tube 3 can be clamped with an arterial clamp 9 that is activated by the control unit 13 of the monitor, which is not shown. The clamp 9 may, for example, be formed as an electromagnetically operable clamp and be operated by the control unit 13 of the monitor in case of alarm to pinch off the tube, and consequently to prevent further blood from being taken from the patient.

The blood that is passed through the dialyser 1 and cleaned there is sent back to the patient via a venous tube 5. An electromagnetically operable venous clamp 11, that is controlled in the same way by the control unit 13 of the monitor, is likewise disposed on the tube 5.

A detector 20 is arranged upstream of the clamp 11 in the direction of flow, and is also connected to the control unit 13 of the monitor. This detector 20 determines on the one hand the presence of the tube 5, and on the other, the characteristic of the content of the tube 5. If, for example, the detector 20 ascertains that the tube 5 contains rinsing liquid, or that air bubbles are contained in the blood being sent back to the patient, an alarm is generated by the control unit 13 of the monitor and the clamps 9 and 11 are activated to pinch off the tubes 3 and 5, respectively. In this way any endangerment to the patient is obviated and the patient's safety improved.

The arrangement of the detector 20 depicted here is only an illustrative example. It is not intended to limit the utilisation of the detector to the arrangement described here within a dialysis monitor, nor to its use only in a dialysis monitor or only in an extracorporeal blood circuit. For example, in addition to its utilisation in haemodialysis, haemodiafiltration and haemofiltration the apparatus can be employed inter alia during plasmapheresis, intravenous infusion, the exchange of blood components or the oxygenation during heart operations.

In Fig. 2, a preferred embodiment of the detector 20 is schematically shown in section. The detector 20 comprises a circuit board 22 on which the electrical components and circuits are arranged, and which is connected by an electrical connection 24 to the control unit 13 (Fig. 1) of the monitor, that is illustrated only by its housing 32. The circuit board 22 with its electrical components and circuits is disposed inside the housing 32 for protection. A light emitting diode (LED) 26 is provided as a light source on the circuit board 22. The LED 26 is combined with a phototransistor 28 and a waveguide 40, this arrangement forming the aforementioned reflection sensor. Furthermore, a sensor 30 that is responsive to the light emitted by the LED 26 is arranged on the circuit board 22.

The detector 20 further comprises a tube or conduit holder 34 that is arranged on the outside of the monitor housing 32 and can hold a tube that is not shown. The conduit holder 34 comprises a recess 36 that tapers inwardly and then opens up to an essentially cylindrical enlargement 38. This enlargement 38 receives the tube that is not shown and holds this in the conduit holder 34. The waveguide 40 connected to the LED 26 and the phototransistor 28 is guided by the monitor housing 32 and the conduit holder 34 up to the enlargement 38, so that light emitted from the LED 26 is guided towards the enlargement 38. A second waveguide 42 is likewise provided in the conduit holder 34 and arranged therein such that one end is directed towards the enlargement 38,

and the other towards the sensor 30. To this end, corresponding openings are provided in both the monitor housing 32 and the conduit holder 34. At the same time, the end of the waveguide 42 directed towards the enlargement 38 is arranged to oppose the first waveguide 40. In this way, the second waveguide 42 can receive the light transmitted towards the enlargement 38 by the first waveguide, and pass this on to the sensor 30.

This is schematically illustrated in Fig. 3. Fig. 3 shows the enlargement 38 of the conduit holder 34 in section, with a tube 5 that has been inserted through the recess 36 of the enlargement. The light rays 50 transmitted by the light source, which is not shown here, are transmitted through the first waveguide 40 to the enlargement 38 and the tube 5 located therein. A portion of the light rays 50 will be reflected at the tube 5, as is illustrated by the arrow 52. These light rays 52 will be detected by the phototransistor 28, which is also not shown here and which then generates a signal and sends this to the control unit of the monitor, both of which are not shown here. This signal simply and reliably indicates that a tube 5 is located in the conduit holder 34, as has been described in detail above.

A portion of the light rays 50 will be transmitted through the transparent tube 5 and will reach the second waveguide 42 arranged opposite. This guides the light rays 50 further to the sensor 30 (Fig. 2), which generates a signal dependent on the intensity of the received light radiation 50 and passes this on to the

control unit of the monitor. This signal simply and reliably indicates the characteristic of the fluid contained in the tube 5. As described above in detail, with this arrangement, the safe and reliable determination of whether the tube 5 is filled with air, with rinsing liquid or with blood, and whether the blood possibly contains air bubbles is enabled.

The arrangement depicted here in which the first waveguide 40 touches the tube 5 is only one embodiment of the apparatus according to the invention. It is also possible to arrange the first waveguide 40 such that it is spaced from the tube 5 located in the enlargement 38.

This is shown in Fig. 4. In the embodiment illustrated here, an air gap 62 is present between the tube 5 and the end of the waveguide 40 directed towards the recess 38 when a tube 5 is inserted in the conduit holder 34. This embodiment differs from that shown in Fig. 3 only in the air gap 62. Like parts are denoted by like reference numerals, so that no renewed detailed description is necessary here.

The air gap 62 can, for example, be implemented using spacers which are not shown in the drawing and which hold the tube at a certain distance from the waveguide 40 to form the illustrated air gap 62. It is also possible that the waveguide 40 comprises one or more recesses at its end that is directed towards the tube 5, so that the tube 5 lies against the projecting parts of the waveguide 40, while an air gap is formed between the recesses in the

waveguide 40 and the tube 5.

The thus formed air gap may be necessary for certain materials or with a certain surface characteristic or shape of the tube 5 to ensure sufficient reflection of the light rays, that is dependent on the refractive indexes of the adjacently arranged materials in the direction of the light ray 50.

In Fig. 5 there is shown schematically part of the control unit 13 and parts of the venous tube 5 with the fitted venous clamp 11 and the photoelectric section of the apparatus according to the invention. The tube 5 may be formed totally, or in the region of the photoelectric section, with a cylindrical or even an oval cross section and be of PVC or another conventional, transparent material used in the medical field. However, it is also possible that the tube be formed as a cell, for example of glass, with a rectangular cross section. The photoelectric section has already been described in detail with reference to Fig. 2, so that a renewed explanation is not necessary. The photoelectric section is shown schematically here, without the waveguide, only with the light source 26, the phototransistor 28 and the first sensor 30. The light source 26 sends light rays 50 towards the tube 5, these are transmitted through the transparently formed tube 5 and are detected by the first sensor 30. A portion of the light rays 50, denoted by 52, are reflected by the tube 5 and detected by the second sensor, the phototransistor 28.

The illustrated portion of the control unit 13 comprises a CPU, a D/A converter, a modulator M, three demodulators DM1, DM2 and DM3, a bandpass filter BF and three comparators K1, K2 and K3. The CPU controls the modulator M that modulates the LED control current via the D/A converter. This has the effect that the light source 26 emits light rays 50 with a predetermined modulation, as described in detail above.

The modulated light rays 50 passing through the tube 5 are detected by the first sensor 30. This then emits a signal which is demodulated by the demodulator DM1. In this way, the influence of the surrounding light on the measurement in the photoelectric section is substantially excluded. The demodulated signal is then passed to the comparator K1, where it is compared with a predetermined value. This predetermined value is supplied from the CPU via the D/A converter to the comparator K1. It should be noted at this point that one embodiment only is being described here, and the predetermined value, the so-called 'trigger value', could also be fed to the comparator in another manner.

If the signal supplied to the comparator K1 by the demodulator DM1 lies above this predetermined value, then either no tube 5 is present, or the tube is present and filled with transparent fluid, so that the same amount of light reaches the first sensor 30 as when the tube 5 is absent as a result of the lens effect described in detail above.

To differentiate between these two situations the CPU uses the signal delivered by the second sensor 28. This responds to the light rays 52 reflected by the tube 5, and emits a signal that is demodulated by the demodulator DM3 and then sent to a comparator K3. This comparator K3 compares the signal delivered by the sensor 28 with a predetermined value, which is supplied by the CPU via the D/A converter. If the signal lies below this value, then no tube 5 is present that could reflect light to the sensor 28. If the signal lies above the predetermined value, then a tube 5 is present, and light 52 is reflected towards the sensor 28, which then emits a signal at a high level. Thus, the CPU can decide with the help of the comparators K1 and K3 whether no tube 5 is present, or whether a tube is present that contains transparent fluid.

In the same way the CPU can determine whether the tube 5 is filled with blood or is empty. To this end, the signal sent to the comparator K1 is compared with a second, low predetermined value. If the signal lies below this value, blood is present in the tube 5. In this case the light ray 50 will be substantially completely filtered, so that the sensor 30 supplies only a correspondingly low signal. If the tube is present, but empty, i.e. filled with air, the light rays 50 will be somewhat filtered and a corresponding signal will be sent by the sensor 30 to the comparator K1. If this signal lies below the first predetermined value and above the second predetermined value, then an empty tube is present. Hence, with the aid of the comparator K1, the CPU can also determine if an

empty tube is present.

Finally, with the help of the comparator K2 the CPU can determine whether air bubbles are present in the fluid flowing through the tube 5. If, for example, air bubbles are present in blood flowing through the tube 5, then as these pass the photoelectric section they will allow the light rays 50 to reach the sensor 30 unhindered to a greater or lesser extent depending on their size. The latter then generates a pulse-like signal corresponding to the passing bubbles. This signal emitted by the sensor 30 is sent both to the comparator K1, as described in detail above, and to the comparator K2 via the demodulator DM2 and the bandpass filter BF. The comparator K2 compares the signal with a predetermined value, and air bubbles are present when the signal lies above this value. In this case the CPU controls, for example, the venous clamp 11, which closes the tube 5. In this way any endangerment of the patient is excluded.

CLAIMS

1. Apparatus for determining the presence of a fluid conduit (5) and at least one characteristic of the content of the fluid conduit (5), the apparatus being disposed on a control device, for example for the extracorporeal treatment of blood, and comprising a light source (26), the radiation (50) of which is directed towards the fluid conduit (5) and through the same, and an optical sensor (30) that detects the radiation (50) emitted by the light source (26) and transmitted through the fluid conduit (5), **characterised by** a second optical sensor (28), that detects radiation (52) emitted by the light source (26) and reflected by the fluid conduit (5).

2. Apparatus according to claim 1, **characterised in** that the second optical sensor (28) is formed integrally with the light source (26).

3. Apparatus according to claim 1 or 2, **characterised in** that the apparatus is arranged with at least its electrical components (22, 24, 26, 28, 30) in a housing (32) of the control device.

4. Apparatus according to any previous claim, **characterised in** that there is provided a first waveguide (40) that transmits light (50) from the light source (26) to the fluid conduit (5), and transmits back light (52) reflected by the fluid conduit (5) to the second optical sensor (28), and a second waveguide (42) that transmits light directed towards the fluid conduit (5) and transmitted through the same towards the first optical sensor (30).

5. Apparatus according to claim 4, **characterised in** that the apparatus comprises a conduit holder (34) arranged on the housing (32) of the control device, the first and second waveguides (40, 42) being integrated in the conduit holder (34).

6. Apparatus according to claim 4 or 5, **characterised in** that the first waveguide (40) is arranged such that an air gap is formed between the fluid conduit (5) and the first waveguide (40).

7. An apparatus according to any previous claim, **characterised in** that the light source (26) emits radiation with a defined wavelength and a defined modulation.

8. An apparatus according to claim 7, **characterised in** that the light source (26) emits radiation in the infrared wavelength region in an essentially square pulse sequence.

9. An apparatus according to any previous claim, **characterised in** that the first and second sensors (30, 28) are electrically connected to a control unit (13) of the control device.

10. An apparatus according to claim 9, **characterised in** that the control unit (13) is formed such that it compares the signals supplied by both sensors (30, 28) with predetermined values, and determines that

- no fluid conduit (5) is present when the signal from the first sensor (30) is at a high level and the signal from the second sensor (28) is at a low level,
- a fluid conduit (5) is present and empty when the signal from the first sensor (30) is at a medium level and the signal from the second sensor (28) is at a high level,
- a fluid conduit (5) is present and filled with transparent fluid when the signal from the first sensor (30) is at a high level and the signal from the second sensor (28) is at a high level,
- a fluid conduit (5) is present and filled with blood when the signal from the first sensor (30) is at a low level and the signal from the second sensor (28) is at a high level,
- a fluid conduit (5) is present and filled with blood and the blood contains air bubbles when the signal from the first sensor (30) is at a low level and the signal from the second sensor (28) is at a high level, and the signal from the first sensor (30) comprises pulses at a high level,

- an error condition exits when the signal from the first sensor (30) is at a low or medium level and the signal from the second sensor (28) is at a low level.

11. An apparatus according to any of the previous claims, **characterised in** that the control device, on which the apparatus is arranged, is a dialysis monitor.

12. A method for determining the presence of a fluid conduit (5) and at least one characteristic of the content of the fluid conduit (5), the method being utilised in a control device, such as for the extracorporeal treatment of blood, and in which radiation (50) from a light source (26) is directed towards the fluid conduit (5) and transmitted through the same, and an optical sensor (30) detects light emitted by the light source (26) and transmitted through the fluid conduit (5), **characterised in** that the radiation (52) emitted by the light source (26) and reflected by the fluid conduit (5) is detected by a second optical sensor (28).

13. A method according to claim 12, **characterised in** that the signals supplied by both sensors (30, 28) are sent to a control unit (13) that compares the signals with predetermined values and determines that

- no fluid conduit (5) is present when the signal from the first sensor (30) is at a high level and the signal from the second sensor (28) is at a low level,
- a fluid conduit (5) is present and empty when the signal from the first sensor (30) is at a medium level and the signal from the second sensor (28) is at a high

level,

- a fluid conduit (5) is present and filled with transparent fluid when the signal from the first sensor (30) is at a high level and the signal from the second sensor (28) is at a high level,
- a fluid conduit (5) is present and filled with blood when the signal from the first sensor (30) is at a low level and the signal from the second sensor (28) is at a high level,
- a fluid conduit (5) is present and filled with blood and the blood contains air bubbles when the signal from the first sensor (30) is at a low level and the signal from the second sensor (28) is at a high level, and the signal from the first sensor (30) comprises pulses at a high level,
- an error condition exits when the signal from the first sensor (30) is at a low or medium level and the signal from the second sensor (28) is at a low level.

Fig.1

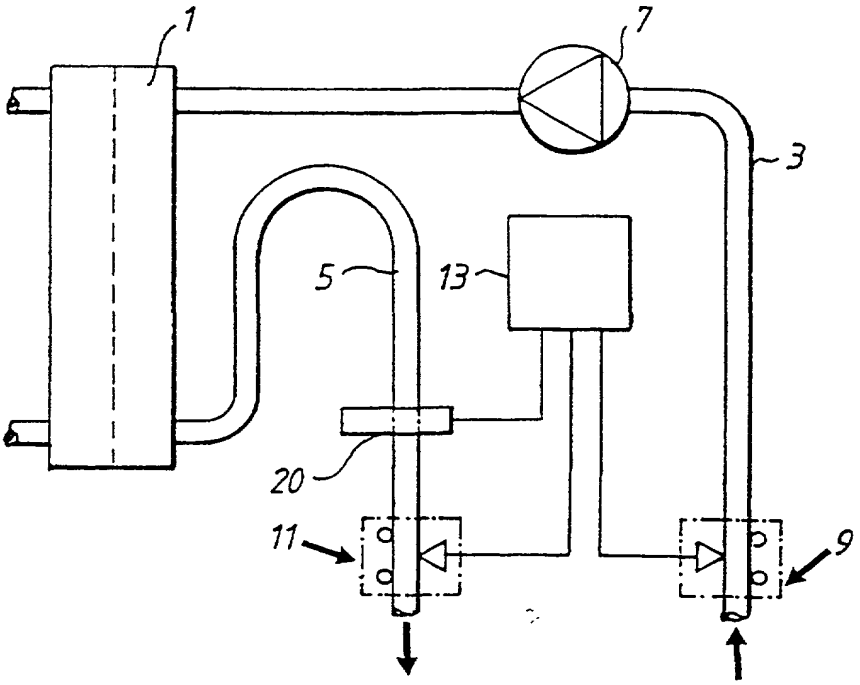


Fig. 2

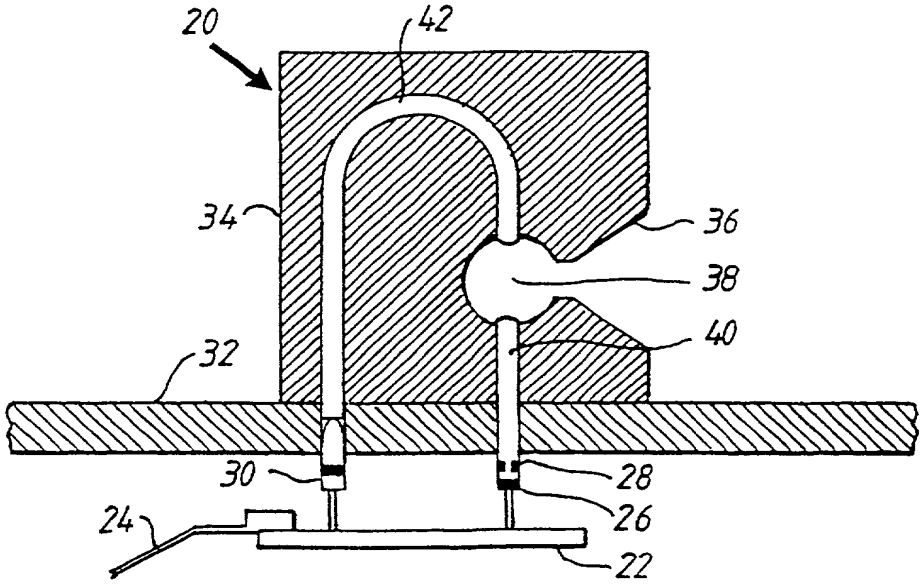


Fig.3

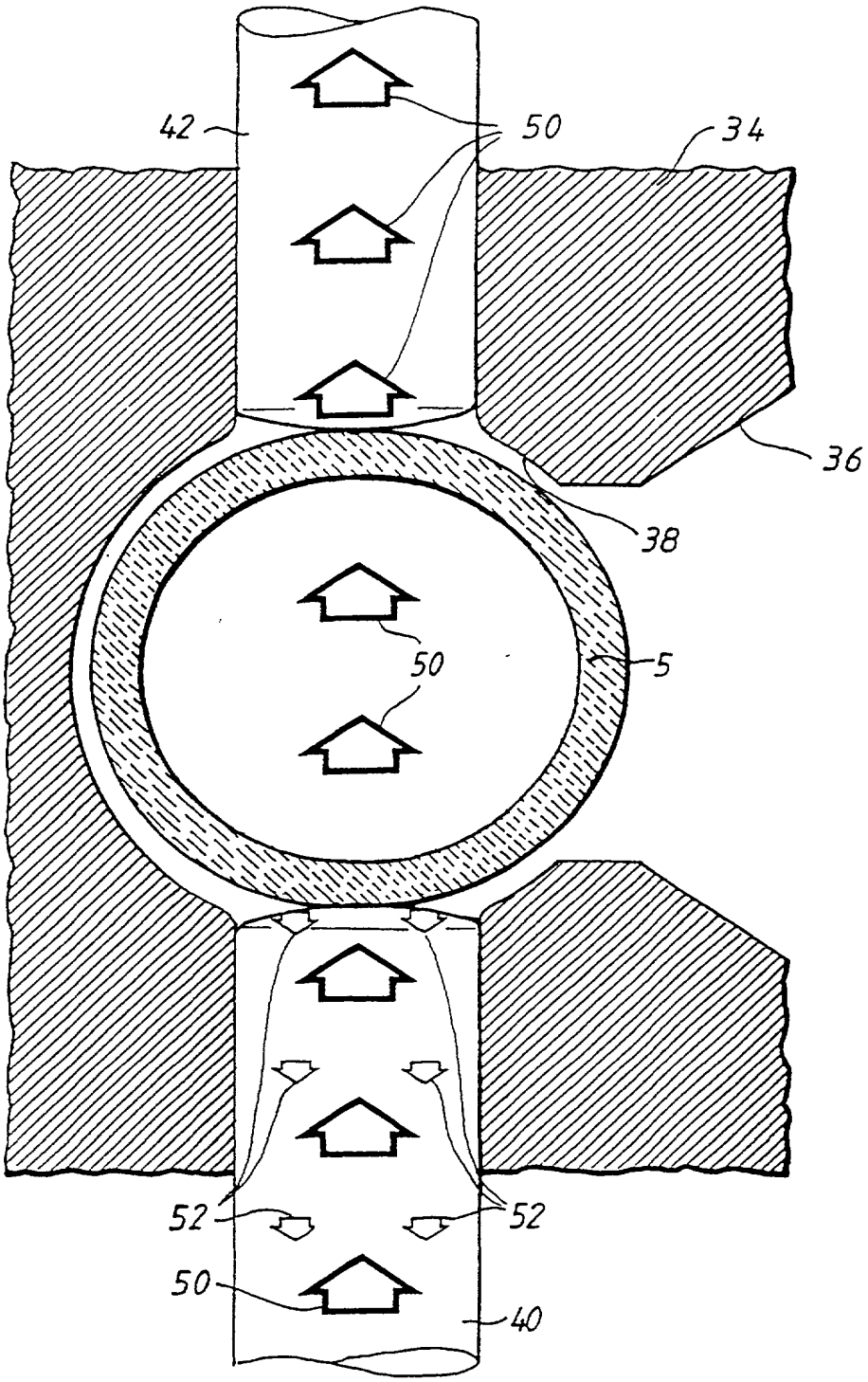
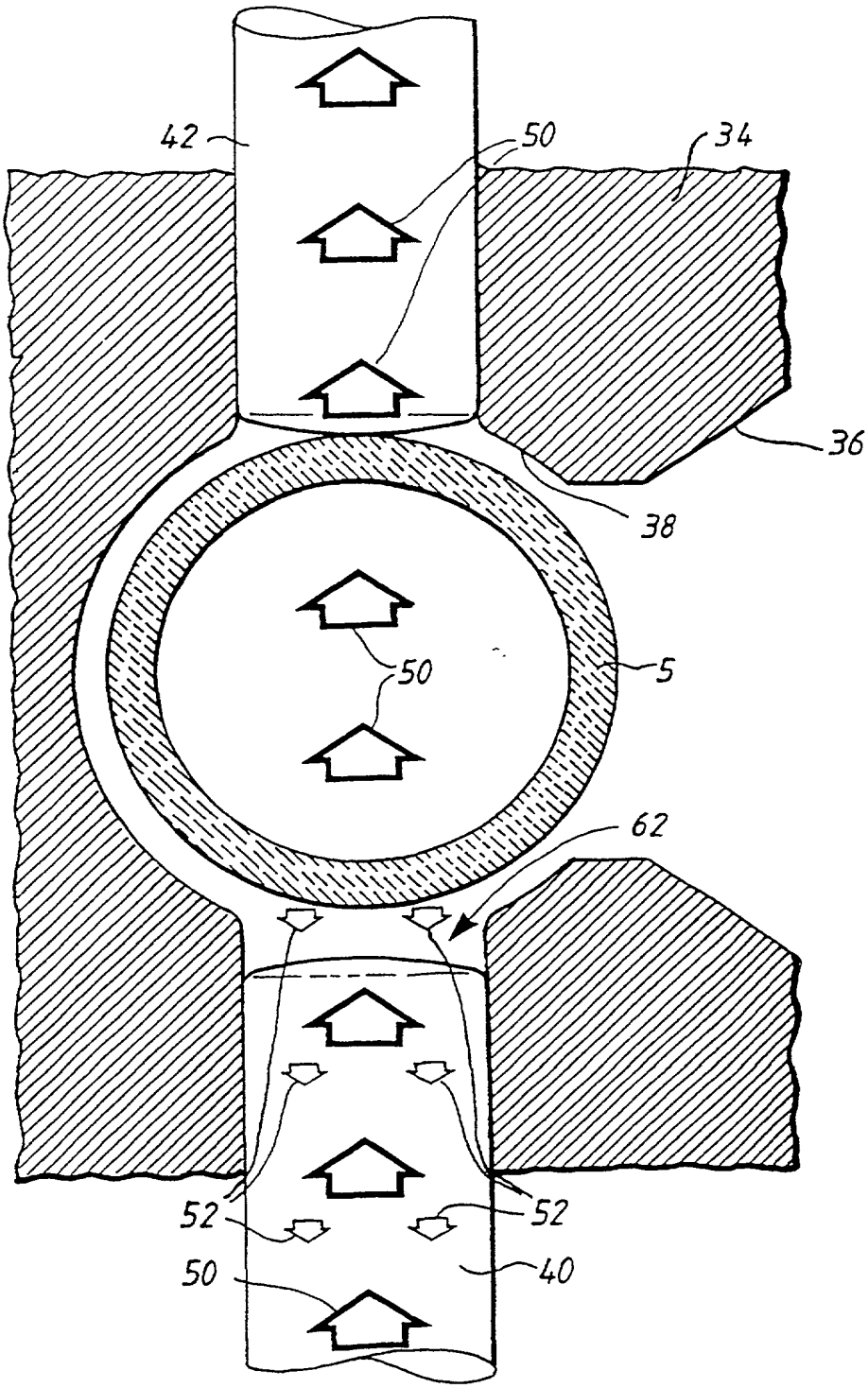


Fig. 4



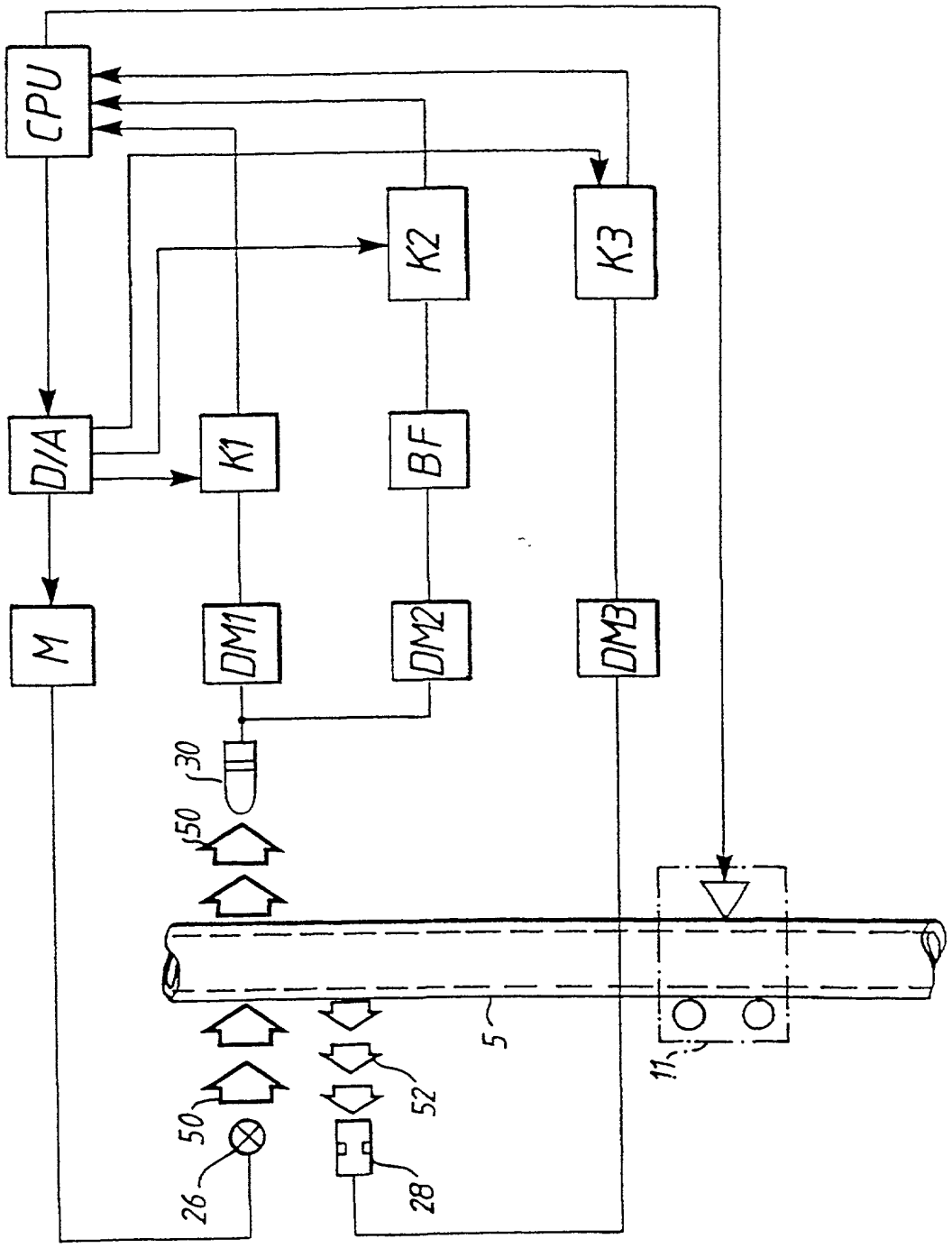


Fig.5

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

ATTORNEY'S DOCKET NO.: GAMBRO 3.3-250

As a below-named inventor, I hereby declare that:
My residence, mailing address and citizenship are as stated below next to my name;
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:
APPARATUS FOR MONITORING A FLUID CONDUIT the specification of which

☐ is attached hereto

☒ was filed on Septebmer 6, 1999 as United States Application Number or PCT International Application Number PCT/SE99/01541 and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)			
COUNTRY	**APPLICATION NUMBER**	**DATE OF FILING (month, day, year)**	**PRIORITY CLAIMED**
Sweden	9803055-4	September 10, 1998	YES ☒ NO ☐
			YES ☐ NO ☐
			YES ☐ NO ☐
LISTING OF FOREIGN APPLICATIONS CONTINUED ON PAGE 3 HEREOF ☐ YES ☒ NO			

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Application Number: Filing Date:

Application Number: Filing Date:

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

U.S. Parent Application Serial Number: Parent Filing Date: Parent Patent No.:

U.S. Parent Application Serial Number: Parent Filing Date: Parent Patent No.:

PCT Parent Number: Parent Filing Date:

LISTING OF US APPLICATIONS CONTINUED ON PAGE 3 HEREOF: ☐ YES ☒ NO

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number 000530

DIRECT ALL CORRESPONDENCE TO: Customer No. 000530

DECLARATION -- Page 2

ATTORNEY DOCKET NO. GAMBRO 3.3-250

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1-00 Full name of sole or first inventor (given name, family name): Olof EKDAHL

Inventor's signature _____ **Date** 2001-03-19

Residence: Lund, Sweden Citizenship: Sweden SEX

Mailing Address. Magistratsvägen 55 S:308, SE-222 38 Lund, Sweden

Full name of second joint inventor, if any (given name, family name) Per-Ola WICTOR

2-00 **Second Inventor's signature** _____ **Date** 2001-03-19

Residence: Stehag, Sweden Citizenship: Sweden SEX

Mailing Address. Mossabäcksvägen 22, SE-240 36 Stehag, Sweden

Full name of third joint inventor, if any (given name, family name):

Third Inventor's signature _____ **Date** _____

Residence: Citizenship:

Mailing Address:

Full name of fourth joint inventor, if any (given name, family name):

Fourth Inventor's signature _____ **Date** _____

Residence: Citizenship:

Mailing Address:

Full name of fifth joint inventor (given name, family name):

Fifth Inventor's signature _____ **Date** _____

Residence: Citizenship.

Mailing Address:

Full name of sixth joint inventor, if any (given name, family name):

Sixth Inventor's signature _____ **Date** _____

Residence: Citizenship:

Mailing Address:

Full name of seventh joint inventor, if any (given name, family name):

Seventh Inventor's signature _____ **Date** _____

Residence: Citizenship:

Mailing Address:

Full name of eighth joint inventor, if any (given name, family name):

Eighth Inventor's signature _____ **Date** _____

Residence: Citizenship.

Mailing Address:

☐ Additional inventors are being named on separately numbered sheets attached hereto.